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# IMPROVED GUIDEWIRE

## BACKGROUND OF THE INVENTION

### 1. Field of the Invention

The invention relates to medical guidewires.

### 2. Description of Related Art

Guidewires are well known in the medical art and are used for accessing distal sites within the human body. Common access routes include the digestive tract, urinary tract, and peripheral, cerebral, and visceral vasculature. In use, the guidewire is inserted into a vessel in the patient and maneuvered to a desired target site in the patient's body. Once in place, the guidewire is used to guide other apparatus, such as a catheter, to the target site. This is accomplished by feeding the catheter or other apparatus over the guidewire until [the] it reaches the target site.

Structurally, guidewires commonly have a core wire having a reduced diameter distal section extending a minority of the guidewire's overall length, and a constant diameter proximal section, extending a majority of the guidewire's overall length. The core sections are manufactured by selecting a single drawn/spooled wire of a diameter equal to the largest diameter section of the desired guidewire, which is generally the proximal section. The spooled wire is then straightened and cut to length, creating a mandrel. The distal segment only of the mandrel is then center-less ground to the desired distal diameters, while the drawn surface of the proximal section is left undisturbed. The core thus produced is further processed into a finished guidewire, including possible coating, or the addition of a helical coil wound over a portion of the guidewire, typically the distal portion.

One important characteristic of a guidewire, especially that used for accessing small, tortuous, distal sites, is the guidewire's ability to transmit one-to-one torque from the proximal portion of the wire extending from the patient's body, to the distal tip of the guidewire. Faithful transmission of torque is important because it determines the ability of the operator to manipulate the implanted, inaccessible distal end of the guidewire by control and manipulation of the unimplanted, proximal end thereof.

For small, long guidewires accessing distal sites through complex/severely tortuous paths, one-to-one torque response is hindered by two major factors. The first of these is whipping of the guidewire, related to the manufacturing limitations associated with straightening and processing a small diameter wire. The second is surface friction over the length of inserted wire associated with the limited ability of the guidewire's drawn surface to be uniformly and durably coated with a desirable friction reducing substance.

Material stiffness and deflection can be explained with reference to FIG. 1 and the following equation:

$$y = (FL^3)/3EI$$

where y is the deflection, F is the force applied, E is Young's modulus for the material used, and I is the moment of inertia (for a bar of circular cross section, $I = D^4/64$, with D being the diameter of the bar).

Assuming that force, length, and cross sectional area are constant, then materials with lower Young's modulus will bend more, or conversely, materials with higher Young's modulus will be stiffer. Similarly, wires with smaller diameters will bend more, or larger forces will cause greater bending. Consequently, the stiffness, or amount of force it takes to bend the wire varies with the fourth power of the diameter of the core wire, and the Young's modulus can be used to predict the usefulness of

different materials. As an example, titanium wire of equal diameter to a stainless steel wire would have 1/4 the stiffness due to the difference in their Young's moduli.

Torsional loads can be modeled in a similar manner. FIG. 2 is analogous to holding a wire at one end and twisting at the other end to cause the tip to turn. The twisting action places the wire under a torque load condition. The applicable equation here is:

$$\phi = TL/GJ$$

where $\phi$ is the angular deflection, T is the torque, L is the length of the wire, G is the modulus of rigidity, and J is the polar second moment of the area (for a bar of circular cross section, $J = \pi D^4/32$).

For good torque control a material with a high modulus of rigidity will provide less angular displacement (less windup), of the distal tip given that all other variables are constant. Additionally, the second polar moment of area relates the diameter of the wire to torque response. As the diameter decreases the angular deflection, windup, increases at a rate to the fourth power. Consequently, small changes in diameter make large changes in torque control.

As seen from the above, small changes in diameter make a significant change in the functional properties; stiffness and torque control. The smaller the diameter of a wire, the more flexible the wire becomes. This is why the tip of guidewires are tapered to provide the additional flexible region for negotiating tortuous vessels. However, it is to be understood that the decrease in diameter of the wire at the tip also decreases the amount of torque control. Consequently, there is a balance to the design of a guidewire which typically favors increased flexibility at the expense of torque control.

## BRIEF SUMMARY OF THE INVENTION

The present invention overcomes whipping problems and coating limitations of prior art guidewires. Whipping problems are overcome by selecting drawn/spooled wire of a diameter greater than the largest diameter section of the desired guidewire. This larger spooled wire is then straightened and cut to length, creating a mandrel. The entire length of the mandrel is then center-less ground to the distal and proximal diameters. The initial larger diameter of this wire ultimately results in a mandrel which overcomes limitations of the straightening process and results in a guidewire which is less prone to whipping and which provides more faithful torque transmission across its length.

A further advantage of the present invention is due to the entire length of the core having a ground surface, as opposed to a very smooth and shiny surface of conventional drawn wire. The ground surface of the proximal section wets-out more easily and uniformly than the drawn surface of prior art guidewire, as well as providing more surface area for coating attachment. This translates to more options of coating materials, more uniform coating distribution, and stronger coating attachments.

Another advantage provided by the present design is improved user interface. This comes by leaving the proximal-most segment of the guidewire uncoated, providing the operator with a surface which is much easier to grasp/torque.

## BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

FIG. 1 is a schematic diagram illustrative of a cantilevered beam subjected to bending force;

FIG. 2 is a schematic diagram illustrative of a rod under torque force;

FIG. 3 is a schematic diagram of a spooled wire from which a mandrel in accordance with the invention is made;

FIG. 4 is a schematic diagram of the cut and straightened spooled wire of FIG. 3;

FIG. 5 is a schematic diagram of a shaped mandrel in accordance with the invention;

FIG. 6A is a cross-sectional view taken along line 6A - 6A of FIG. 5;

FIG. 6B is a cross-sectional view of a non-round mandrel in accordance with the invention;

FIG. 7 is a schematic diagram of a coil used in a guidewire in accordance with the invention; and

FIG. 8 is a schematic diagram of a completed guidewire product formed in accordance with the invention.

## DETAILED DESCRIPTION OF THE INVENTION

In accordance with the present invention, a guidewire is manufactured using a segment of drawn/spooled wire which is straightened and cut to an appropriate length. The segment, which is initially of a first, constant diameter $D_i$, is ground down or otherwise shaped into a mandrel, or core, comprised of one or more segments k having corresponding diameter(s) $D_1$-$D_k$. The diameters $D_1$-$D_k$ may vary, but largest of these, or the maximal diameter $D_M$, is smaller than the initial diameter $D_i$. One or more coatings are optionally applied to one or more of the segments. Additionally, a helical coil can be wound around portions of the mandrel, or core, preferably a portion comprising a distalmost segment of the mandrel. FIGS. 3-5, 6A, 6B, 7, and 8 illustrate this process.

FIG. 3 shows a spool 10 of wire 12 conventionally available from various commercial wire manufacturers. The wire 12 can be metallic, such as stainless steel or titanium, or made from other alloys or materials. $D_i$ indicates the diameter of this wire, which is selected in accordance with the contemplated application of the finished guidewire product. It will be appreciated, for instance, that applications in the cerebral vasculature will require relatively small diameters, while those for cardiosurgical applications can have relatively larger diameters.

The wire 12 from spool 10 is then straightened and cut to an appropriate length L, schematically shown in FIG. 4, with length L corresponding generally to the contemplated guidewire application and to the patient size. Subsequently, the wire 12 is preferably center-less ground, but can be otherwise shaped, to form a substantially cylindrical mandrel 14 having one or more segments k of varying diameters, all of which are smaller than the initial diameter $D_i$ of the wire 12. In other words, the maximal diameter $D_M$ of the mandrel is smaller than $D_i$, or $D_M < D_i$. In FIG. 5, three segments—16, 18 and 20—are shown, having respective diameters $D_1$-$D_3$, with the inequalities $D_1 < D_i$, $D_2 < D_i$ and $D_3 < D_i$ being applicable. Although as exemplarily shown in FIG. 5 proximal segment 16 has the largest diameter, with those of segments 18 and 20 being progressively smaller, it is within the scope of the invention to have a different relative arrangement of the segments and their corresponding diameters. The lengths of the segments are also functions of the desired application. Typically, the proximalmost segment (16) is about 30 cm in length.

While the segments k of mandrel 14 are described as being generally round in cross section, it is to be understood that other cross-sectional shapes, such as oval or elliptical, can be used for any or all of the segments k of mandrel 14. FIG. 6A illustrates the round cross-sectional shape of segment 20, while FIG. 6B shows an alternative oval cross-sectional shape of a section 20' of a mandrel 14'.

After forming mandrel 14, it may be desirable to helically wind a coil such as coil 22 shown in FIG. 7 over a portion of the mandrel 14. Coil 22 is formed of any suitable material, but is preferably of platinum or other radiopaque material. Coil 22 serves to render the portion of the guidewire to which it is attached visible during surgical procedures, or to impart rigidity and torquability, among other physical characteristics, to the section of the guidewire over which it is wound. As shown in FIG. 8, coil 22 is wound over the distal portion 24 of the resulting guidewire 26, corresponding to section 20 of mandrel 14 (FIG. 5), whose ground down dimensions are selected to accommodate the added thickness of the coil 22 wound thereover. Coil 22 is affixed to the core by soldering and/or adhesive means.

Finally, one or more coatings (not shown) may be applied to the guidewire 26 or to selected portions thereof. To increase friction with the operator's hand and thereby facilitate handling, proximal portion 28 of the guidewire 26 is left uncoated, as compared with the remainder of the guidewire, which is preferably treated with a known lubricious coating such as Teflon™ or other hydrophilic material. It is also known to attach a handle (not shown) at proximal portion 28 to further facilitate handling.

The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to those of ordinary skill in the art that modifications thereto can be made without departure from the spirit and scope of the invention as set forth in the following claims.